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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/884,728	06/19/2001	Clifford J. Dwyer	CRD-0940	3625
27777	7590	11/10/2004	EXAMINER MILLER, CHERYL L	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/884,728	Applicant(s) DWYER ET AL.	
	Examiner Cheryl Miller	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9, and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments filed October 18, 2004 have been fully considered but they are not persuasive. Applicant has argued that the references used in the previous rejection, taken alone or in combination do not teach a delivery apparatus comprising stainless steel flat wire. The examiner disagrees. Motivation for flat/rectangular wire having the size and shape is believed to be clearly stated in the previous rejection and has been maintained (see below for further elaboration). Gerdts clearly states motivation for having a flat wire, for the purpose of having smaller dimensions, giving the apparatus a lower profile shape for easy insertion, and to increase the mechanical properties of the apparatus (col.3, lines 1-10; col.5, lines 49-65; col.7, lines 28-42). Further, it is noted to the applicant that even without the teaching of Gerdts, this would be a mere obvious change of size and shape, see *In re Rose* 220 F.2d 459, 105 USPQ 237 (CCPA 1955), *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976), and *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-9 and 12-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "the self-expanding stent" in lines 5-6. There is insufficient antecedent basis for this limitation in the claim. Although a self-expanding stent is mentioned in

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the preamble, it is mentioned as intended use language, therefore, a self-expanding stent has not yet been positively claimed. It is suggested to change "the self-expanding stent" to recite --a self-expanding stent--. Claims 9 and 12-15 depend upon claim 1 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilson et al. (EP 1 025 813, cited in previous office action) in view of Gerdtz (US 6,689,120 B1, cited in previous office action). Referring to claim 1, Wilson discloses a delivery apparatus (1) for a self-expanding stent (50) comprising a shaft (10) having a guidewire lumen (28), a stent bed (24), a sheath (40) having an enlarged section (44) coaxial with the stent bed, the sheath (40) including an inner polymeric layer (48), an outer polymeric layer (72), and a wire reinforcement layer (70) made of stainless steel (col.9, lines 40-41) and of any dimension (col.10, lines 13-16). Wilson discloses a delivery apparatus with a wire reinforced sheath substantially as claimed, wherein the wires may have cross-sectional shapes other than circular (col.10, lines 13-16), however does not explicitly disclose rectangular shaped cross sections. Gerdtz teaches in the same field of self-expanding stent delivery apparatuses (16), a sheath (18) having a stainless steel wire reinforcement layer (44) with rectangular cross-sections having the sized claimed (col.3, lines 1-7; col.5, lines 53-59) as an alternative to circular, in order to increase the stiffness of the

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sheath to prevent kinking, while also minimizing the profile for easy insertion (col.3, lines 1-10; col.5, lines 49-65; col.7, lines 28-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Wilson's wire reinforced sheath with Gerdt's geometric teaching of using flat *rectangular* wires within the sheaths, in order to provide reinforcement to prevent kinking while also minimizing profile for easy delivery.

Referring to claim 2, Wilson discloses a reinforcement layer (70), which extends between the inner and outer layers (fig.8).

Referring to claim 5, Wilson has shown a wire arranged in a braided configuration (fig.8; col.9, lines 27-31).

Referring to claims 6 and 7, Wilson discloses an inner polymeric layer comprising PTFE and an outer layer comprising NYLON (col.9, lines 37-41; col.10, lines 49-51).

It is noted to the applicant, that the above Wilson patent qualifies and is being used based on a 102(a) date, therefore may be used in a 103 rejection, even though they may have been commonly owned at the time the invention was made.

Claims 1, 2, 5-9, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raeder-Devens et al. (US 6,726,712 B1, cited in previous office action) in view of Gerdt's (US 6,689,120 B1, cited in previous office action). Referring to claims 1 and 8, Raeder-Devens discloses a delivery apparatus for a self-expanding stent (col.3, lines 26-29) comprising a shaft (40) having a guidewire lumen (fig.2), a stent bed (42), a sheath (18) having an enlarged section (larger diameter at distal end than at medial or proximal end, col.4, lines 28-34; col.5, lines 65-69; col.6, lines 4-6, 22-25) coaxial with the stent bed, the sheath (18) including an inner

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polymeric layer (46), a lubricious coating on the inner polymeric layer (col.5, lines 32-36), an outer polymeric layer (48+50+52), and a stainless steel (col.4, lines 44-46; col.5, lines 39-42) wire reinforcement layer (34). Raeder-Devens discloses a delivery apparatus with a wire reinforced sheath substantially as claimed, however does not disclose rectangular shaped wires. Gerdts teaches in the same field of self-expanding stent delivery apparatuses (16), a sheath (18) having a stainless steel wire reinforcement layer (44) with rectangular cross-sections having the dimensions claimed (col.3, lines 1-7; col.5, lines 53-59), as an alternative to circular, in order to increase the stiffness of the sheath to prevent kinking, while also minimizing the profile for easy insertion (col.3, lines 1-10; col.5, lines 49-65; col.7, lines 28-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Raeder-Devens wire reinforced sheath with Gerdts's geometric teaching of using flat *rectangular* wires within the sheaths, in order to provide reinforcement to prevent kinking while also minimizing profile for easy delivery.

Referring to claims 2 and 9, Raeder-Devens discloses a reinforcement layer (34), which extends between the inner (46) and outer (48) layers (fig.2).

Referring to claims 5 and 12, Raeder-Devens has shown a wire (34) arranged in a braided configuration (fig.2; col.5, lines 39-41).

Referring to claims 6-7 and 13-15, Raeder-Devens discloses an inner polymeric layer comprising PTFE (col.5, lines 14-16, 31-34), an outer layer comprising NYLON (col.5, lines 53-56; col.6, lines 31-39), and a coating comprising silicone (col.5, lines 33-37).

Claims 1, 2, and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (US 6,287,329 B1, cited in previous office action) in view of Gerdts (US 6,689,120 B1, cited in previous office action). Referring to claim 1, Duerig discloses a delivery apparatus for a self-expanding stent (col.1, lines 5-9) comprising a shaft (510) having a guidewire lumen (fig.9), a stent bed, a sheath (540) having an enlarged section (542; col.6, lines 56-67; col.7, lines 5-10) coaxial with the stent bed, the sheath (540) including an inner polymeric layer, an outer polymeric layer, and a stainless steel wire reinforcement layer (sheath 540 being equivalent to sheath 40, col.5, lines 14-29). Duerig discloses a delivery apparatus with a wire reinforced sheath substantially as claimed, however does not disclose rectangular shaped wires. Gerdts teaches in the same field of self-expanding stent delivery apparatuses (16), a sheath (18) having a stainless steel wire reinforcement layer (44) with rectangular cross-sections having the dimensions claimed (col.3, lines 1-7; col.5, lines 53-59) as an alternative to circular, in order to increase the stiffness of the sheath to prevent kinking, while also minimizing the profile for easy insertion (col.3, lines 1-10; col.5, lines 49-65; col.7, lines 28-42). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Duerig's wire reinforced sheath with Gerdts's geometric teaching of using flat *rectangular* wires within the sheaths; in order to provide reinforcement to prevent kinking while also minimizing profile for easy delivery.

Referring to claim 2, Duerig discloses a reinforcement layer, which extends between the inner and outer layers (fig.9; col.5, lines 13-29).

Referring to claim 5, Duerig discloses a wire arranged in a braided configuration (fig.9; col.5, lines 13-29).

Referring to claims 6-7, Duerig discloses an inner polymeric layer comprising PTFE, and an outer layer comprising NYLON (col.5, lines 13-29).

Claims 8, 9, and 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duerig et al. (US 6,287,329 B1, cited in previous office action) in view of Gerdts (US 6,689,120 B1, cited in previous office action) and Raeder-Devens et al. (US 6,726,713 B1, cited in previous office action). Referring to claims 8 and 15, Duerig discloses a delivery apparatus for a self-expanding stent (col.1, lines 5-9) comprising a shaft (510) having a guidewire lumen (fig.9), a stent bed, a sheath (540) having an enlarged section (542; col.6, lines 56-67; col.7, lines 5-10) coaxial with the stent bed, the sheath (540) including an inner polymeric layer, an outer polymeric layer, and a stainless steel wire reinforcement layer (sheath 540 being equivalent to sheath 40, col.5, lines 14-29). Duerig discloses a delivery apparatus with a composite outer sheath with a wire reinforcement layer substantially as claimed, however does not disclose rectangular shaped wires and does not disclose a coating on the inner polymeric layer. Gerdts teaches in the same field of self-expanding stent delivery apparatuses (16), a composite sheath (18) having a stainless steel wire reinforcement layer (44) with rectangular cross-sections having the size claimed (col.3, lines 1-7; col.5, lines 53-59) as an alternative to circular, in order to increase the stiffness of the sheath to prevent kinking, while also minimizing the profile for easy insertion (col.3, lines 1-10; col.5, lines 49-65; col.7, lines 28-42). Raeder-Devens also teaches in the same field of self-expanding stent delivery apparatuses, use of a silicone coating on an inner polymeric layer of composite sheaths, in order to provide a lubricious, low friction surface adjacent the stent, in order to facilitate easy of displacement (col. 5, lines 33-37; col.7, lines 18-

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20). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Duerig's wire reinforced sheath with Gerdts's geometric teaching of using flat *rectangular* wires within the sheaths, in order to provide reinforcement to prevent kinking while also minimizing profile for easy delivery and Raeder-Devens teaching of providing a silicone coating on the inner polymeric layer, in order to provide a lubricious, low friction surface adjacent the stent, in order to facilitate easy of displacement.

Referring to claim 9, Duerig discloses a reinforcement layer, which extends between the inner and outer layers (fig.9; col.5, lines 13-29).

Referring to claim 12, Duerig discloses a wire arranged in a braided configuration (fig.9; col.5, lines 13-29).

Referring to claims 13-14, Duerig discloses an inner polymeric layer comprising PTFE, and an outer layer comprising NYLON (col.5, lines 13-29).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl Miller



BRUCE SNOW
PRIMARY EXAMINER